



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

WASHINGTON STATE BOARD OF PHARMACY
MEETING MINUTES
September 17, 2009
Fife Community Center
2111 54th Avenue E.
Fife, WA 98424

CONVENE

Chair Gary Harris called the meeting to order at 9:02 a.m., September 17, 2009.

Board Members present:

Gary Harris, RPh, Chair

Albert Linggi, RPh

Dan Connolly, RPh

Rosemarie Duffy, RN, MA, MSN, Public Member, Vice-Chair

Vandana Slatter, PharmD

Christopher Barry, RPh

Rebecca Hille, BA-Public Member

Staff Member present:

Joyce Roper, AAG

Susan Teil Boyer, Executive Director

Grant Chester, Chief Investigator

Stan Jeppesen, Investigator

Cathy Williams, Pharmacist Consultant

Tim Fuller, Pharmacist Consultant

Doreen Beebe, Program Manager

Leann George, Program Support

Melissa Burke-Cain, AAG

Guest / Presenters:

Dr. Robin Corelli, PharmD

Rules Hearing

The purpose of this hearing was to solicit public comments for the proposal to add carisoprodol to schedule IV of Chapter 246-887 WAC, Pharmacy – Regulations Implementing the Uniform Controlled Substances Act. The proposed rule was filed with the Code Reviser's office on **August 4, 2009**. Notice was published in the Washington State Register as **WSR # 09-16-119**.

Tim Fuller summarized the proposed rule, further explaining the criteria defined in RCW 69.50.201 for scheduling in substance. Mr. Fuller followed his presentation by answering any questions from the board.

The Chair opened the hearing to public testimony. Testimony was given in support and opposition of the proposal to schedule carisoprodol. The board responded to each testimony and the written comments received regarding the rule change. A copy of the summary of the testimony/comments and board's response will be mailed to individuals upon request.

MOTION: Dan Connolly made a motion that the proposed rule to add carisoprodol to schedule IV of Chapter 246-887 WAC, Pharmacy – Regulations Implementing the Uniform Controlled Substances Act be adopted by the board. Rebecca Hille second. **MOTION CARRIED: 6-0.**

A copy of the summary will be sent to those who signed up for comment.

The adopted rule will become effective 31 days after it is filed with the Code Reviser's office. The hearing was concluded at 10:03 am.

CONSENT AGENDA

- 1.2** Pharmacy & Other Firm Application Approval
 - New Pharmaceutical Firms -7/21/09- 8/31/09
- 1.4** Pharmacy Tech Training Program Approval
 - Bryman College – San Jose, CA- Gary Smith
 - Kaplan College – Palm Springs, CA – Kimberly Kahrs
 - Western Career College – Citrus Heights, CA – Babita Singh
 - Platt College – Oklahoma City, OK – Diane Copeland
- 1.7** Board Minute Approval

Items listed under the consent agenda are considered to be routine agency matters and will be approved by a single motion of the board without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda. **Items 1.1, 1.3, 1.5, 1.6** have been **deleted** from the agenda.

MOTION: Rebecca Hille moved that the board approve items 1.2, 1.4, and 1.7. Vandana Slatter second. **MOTION CARRIED: 6-0.**

REPORTS

Board Member

Al Linggi reported:

- He will be attending the National Association of Boards of Pharmacy (NABP) District meeting in New Orleans.
- He attended the University of Washington Corporate advisory board for the School of Pharmacy. Ryan Hansen co-published a poster showing the economic cost of opioids for the United States for one year. This included the cost for substance abuse treatment, medical complications, productivity loss and what it cost to cover the criminal justice cost. The economic cost total for opioids total is \$53.412 billion dollars. Al suggested that this poster and other documents be brought back to the legislature regarding the prescription monitoring program.

Gary Harris reported:

- At the last board meeting the board approved that Gary Harris and Susan Teil Boyer set up a discussion with Governor Chris Gregoire regarding pharmacy robberies. He sent a request to the governor's appointment person and is still waiting to hear back. Grant Chester and Susan Teil Boyer have put together talking points for this discussion.

Assistant Attorney General

Joyce Roper reported:

- There was a court of appeals decision that may have some implications for the board's processes in one of the board's rules in authorizing certain categories of complaints to be investigated without having to come to the board. The court says it is not appropriate for boards/commissions to delegate categories of cases to staff to investigate. All complaints should go before a panel of the board to decide whether to investigate a case.

Executive Director

Susan Boyer reported:

- October 29, 2009 there will be a Board Strategic Business Planning Session instead of a board meeting. Janet Kastl will be the facilitator for this session. Doreen Beebe, Tim Fuller and Susan Teil Boyer have met with Janet to prepare for this meeting. This will be one full day. Karen Jensen and Steve Saxe will visit during lunch.
- Board meetings will continue on normal schedule December 10, 2009.
- She met with internal staff of the Dept of Health concerning the Death with Dignity Law which allows faxing of CII prescriptions. This conflicts with the federal requirement that does not allow faxing of CII prescriptions. During the discussion the emphasis was on the importance of good communication between the provider and the pharmacist concerning the patient.
- Susan had a meeting with Washington Association of Sheriff and Police Chief's (WASPC) policy director and executive director to discuss the work of their workgroup around policy and procedures for medication management. They have agreed to allow us to review their draft once it is finished.
- The H1N1 is consuming a great deal of time from the Department of Health along with the boards/commissions. Tim Fuller is spending a lot of his time on the antiviral and vaccine workgroup. Susan is on the health care workgroup.
- Department of health was able to provide a rapid license for McKesson to distribute the H1N1 vaccine when it arrives.
- Susan is going to be working with Dick Morrison and Grace Cheung to review questions for the MPJE for use in the state.

Consultant Pharmacists

Cathy Williams reported:

- Regarding the rule to *Extended Prescription Refills Date* Cathy met with Kris Reichl, Margaret Gilbert, and Tami Thompson for a pre-CR101 meeting. They provided excellent feedback. She met with Kris again to prepare a work plan. The plan is to hold stake holder workshops after the December 2009 board meeting.
- She compiled an initial draft of historical information on the board-approved process for granting exemptions to pharmacies that meet certain criteria to dispense drug samples.
- Attended a meeting of the Washington State Medical Agency (WSMA) Directors Group involving Department Of Health (DOH) interagency workgroup on unintentional deaths due to opioids, the WSMA workgroup on opioids, and a presentation made by an Sacred Heart Emergency Room physician in Spokane who's created a network among all the hospital Emergency Rooms in that area.

- ✓ Maxine Hayes was the kick off speaker for this meeting and talked about the Department Of Health interagency group.
- Finalized review forms and guideline document for tech training programs based on the board's approval at the July board meeting.

Tim Fuller reported:

- Emergency Response to Swine Flu Pandemic.
 - ✓ Presentation on pharmacy collaborative agreements, clarification of medication issues.
 - ✓ Working with pharmacy groups to understand the Emergency Response Plan and with the planners to understand pharmacy services.
 - ✓ Assist with distribution of pre-registration form for H1N1 vaccine to pharmacies
- Receiving, Storage, and Staging (RSS) facility.
 - ✓ Responded to Spring event after action plans for more Quality Assurance (QA) volunteers.
 - ✓ As QA Lead working to improve the warehouse operation.
- Board of Pharmacy meeting.
 - ✓ Worked with requestors on proposals for remote order processing to meet the board's expectations for security.
- Rapid licensing of McKesson H1N1 flu vaccine warehouses working with Secretary's office and Customer Service.
- Leadership for Health Systems Quality Assurance (HSQA) in the planning for H1N1 vaccine administrations
- Insured appropriate scope of practice for veterinary technicians.
- Collaborative Drug Therapy Agreements are still a work in progress. A procedure has been developed and everyone is working diligently on the back log.

Chief Investigator

Grant Chester reported:

- Pharmacist Investigators Greg Lang and Tyler Varnum completed the Consumer Products and Safety Commission (CSPC) contract during August. They checked all will call prescriptions in the 10 selected pharmacies to make sure a signature was on file for all containers with easy open caps. Violations are reported to the Food and Drug Administration (FDA), CPSC. The pharmacies receive a letter from the FDA, CSPS notifying them of the results of the inspection and asking them to take corrective action.
- During July and August 2009 we received 20 inspection feedback forms from licensees surveyed during that time period. Each form has room for 6 comments relating to the inspection and 5 relating to the investigator. We received 116 excellent comments and 4 good comments relating to the inspection. There were 100 excellent comments relating to the investigator.
- During a healthcare emergency all of the pharmacist investigators volunteered to participate at the Washington Regional Strategic Stockpiles (RSS) in quality assurance positions. The RSS is responsible for breaking down the material received from the National Strategic Stockpile (NSS) and distributing the material to the Local Health Jurisdictions (LHJ) within Washington State

PRESENTATIONS

Promoting Pharmacy Based Referral to Tobacco Quit-line

Dr. Robin Corelli shared a presentation on pharmacy partnership for tobacco cessation study in Washington.

National Initiative

- Pharmacy partnership for Tobacco Cessation
 - Create and enact a roadmap for pharmacy's future role in tobacco cessation.
 - Focus on brief interventions when time or expertise are barriers to counseling.

Effective Methods for Quitting

- Pharmacotherapy.
- Behavioral counseling.
- Combination therapy yields the highest quit rates.

Licensed Pharmacist's Training for Cessation

- Fewer than 9% have received formal training.
- 88% are interested in receiving training.
- 93% believe it will improve the quality of their counseling.
- 70% believe it will increase the number of patients they counsel.

Study Rationale

- Tobacco is the leading preventable cause of death.
- Patients who smoke require more medications.
- Pharmacies are uniquely positioned to assist patients with quitting.
 - ✓ Frequent contact for medications and refills.
 - ✓ Primary location for sales of smoking cessation medications.

Study Aims

- Estimate the relative impact of two interventions approaches generating community pharmacy-based referrals to the quit line, assessed through measures of the number of:
 - ✓ Quitline referral cards provided to patients in the community pharmacies.
 - ✓ Incoming calls to the quitline originating from each participating pharmacy.
 - ✓ Quitline counseling registrants that come from each pharmacy.
- Identify variable associated with self-reported quitline referral practices among pharmacy personnel.

Study Timeline

- Surveys will be given to pharmacy personnel baseline after 3 months and 6 months.
- On-site quitline card counts at 3 months and 6 months.
- Quitline calls and registrations monitored by Free & Clear for 12 months with primary outcomes at 3 months and 6 months.

Intervention Groups

- Minimal intervention will consist of printed quitline materials delivered by mail.
- Academic detailing intervention this is a brief on-site training for pharmacist and technicians. Along with the printed quitline materials, fax referral forms and a dvd demonstration which models the Ask-Advise-Refer procedure.

Goal

- The goal is to determine which method is most effective, and most cost-effective.

The board asked Dr. Robin Corelli to send them the outcome data one year after the survey along with a list of the pharmacies that were involved in the survey.

Pharmacy Law Presentation

Grant Chester, Chief Investigator provided a presentation to the Board the *Pharmacy Laws and Regulatory Update- 2009*. This presentation was given at the 2009 Northwest Pharmacy Convention.

Presentation Goals Increase Awareness

- New state requirements for licensure
 - ✓ All in state applicants have a state wide background check
 - ✓ All out of state applicants are required to have a fingerprint based national background check.
 - ✓ This must be completed prior to licensure.
 - ✓ RCW 18.130.064
- Mandatory Reporting
 - ✓ What must be reported: Any conviction, determination, or finding that a license holder has committed an act that constitutes unprofessional conduct.
 - ✓ Who must report: All DOH licensees are required to report, others are encouraged to report.
 - ✓ WAC 246-16-200 thru 265
 - ✓ Examples of reporting requirements.
 - Self reporting and reporting of others required
 - Health care institutions & service contractors
 - Professional review organizations
 - Professional liability insurance carriers & disability insurers
 - Courts and law enforcement
 - ✓ Tamper Evident Prescription Pads
 - ✓ Pads must have certain characteristics
 - Features that prevent unauthorized copying;
 - Features that prevent the erasure or modification of information written by the prescriber.
 - Features that prevent the use of counterfeit forms.
 - ✓ The Washington State legislature passed HB2014 requiring prescription pads to be tamper resistant by July 1, 2010
 - ✓ This rule only applies to prescriptions that will be given to the patient.
 - ✓ A problem has come up that when a practitioner's office faxes a tamper-resistant prescription to a pharmacy it prints out as void in the pharmacy.
 - ✓ The DEA will not accept void prescriptions
 - ✓ Do not assume just because it is on a tamper resistant prescription paper it is a valid prescription.
- Sexual Misconduct
 - ✓ Some violations (part of the 21 listed in rule)
 - Touching any sexualized body part
 - Kissing, hugging, fondling, caressing or rubbing against a patient for sexual gratification
 - Suggesting or discussing the possibility of dating or romantic relationship
 - Soliciting a date with a patient, client or key party.
 - ✓ Other violations
 - Offer to provide health care services in exchange for sexual favors
 - Use health care information to contact the patient, client, etc.
 - ✓ A health care provider shall not engage or attempt to engage, in activities listed with a former patient, client or key party within two (2) years after the provider-patient/client relationship ends.
 - ✓ WAC 246-16-100
- FDA Adverse Event Reporting
 - ✓ Requires all O-T-C drug labels to have a toll free phone number for reporting adverse events. There are 3 options:
 - FDA (1-800-332-1088)
 - Manufacturers

- Distributor
- ✓ Requires all O-T-C drug label to have a “side effects statement”
- ✓ Best Pharmaceuticals for Children Act (BPCA)
- ✓ Issued advisory that includes Dietary Supplements and Non-Approved O-T-C drugs. (September 2009)
- ✓ Effective 1 July 2009
- ✓ Requires pharmacies to notify patients to provide all patients with a “side effects statement” and FDA toll free number by:
 - A sticker attached to the package
 - On a preprinted pharmacy prescription vial cap
 - On a separate sheet of paper
 - With consumer medication information (CMI)
 - Distributing the FDA approved Medication Guide that contains the “side effects statement”
- ✓ Effective 1 July 2009
- ✓ Requires Direct to Consumer Advertising to display in conspicuous text:
 - “You are encouraged to report negative side effects of prescription drugs to the FDA.”
 - Visit www.fda.gov/medwatch or
 - Call 1-800-FDA-1088 (1-800-332-1088)
- ✓ Federal Register 73/229, 11/26/08
- DEA Schedule II and other CS Rules
 - ✓ What can be changed on a C-II prescription?
 - ✓ The prescription must have the correct patient name, drug (brand or generic), and be signed by the practitioner.
 - ✓ In Washington State everything else can be changed after contacting the practitioner and annotating on the prescription that the practitioner was contacted by the pharmacist.
 - ✓ Per letter dated 10/15/08 from DEA.
 - ✓ DEA now allows multiple prescriptions on the same day with instructions to fill on different dates (30 days supply, max of 90 days total)
 - ✓ DEA does not allow electronic transmission of schedule drug prescriptions, pharmacist must call
 - ✓ The DEA requires the prescriptions be written on separate blanks. They do not allow 3 prescriptions on the same prescription blank.
 - ✓ The practitioner can put two non-multiple C II prescriptions on the same blank, but no other drugs.
- Death with Dignity Act (I-1000)
 - ✓ Only willing health care providers...
 - ✓ The physician must contact a pharmacist and inform the pharmacist of the prescription; and deliver the written prescription personally, by mail, or (facsimile) to the pharmacist.
 - ✓ The pharmacist will then dispense the medications directly to either the patient, the attending physician, or an expressly identified agent of the patient.
 - ✓ Medications dispensed pursuant to this subsection shall not be dispensed by mail or other form of courier.
 - ✓ The pharmacist must complete the “Pharmacy Dispensing Record” DOH Form 422-067/CHS 605 and mail it to the State Registrar.
 - ✓ RCW 70.245 and WAC 246-978 or www.doh.wa.gov/dwda
- Patient Specific Information Handling
 - ✓ It is unprofessional conduct to violate a patient’s privacy.

- Do not discuss patient info inappropriately
 - Safeguard information stored in computer
 - Properly dispose of leaflets and labeled vials
- ✓ WAC 246-863-095
- ✓ You should also consider the proper disposal of pharmacy information
- Other Miscellaneous Info of Interest
 - ✓ Abuse Behavior
 - ✓ Pharmacy Inspection Deficiencies
 - ✓ Complaint Process
 - ✓ Patient Counseling
- The DEA is currently reviewing proposals for electronic transmission
 - ✓ The DEA does not allow for the electronic transmission of controlled substance prescriptions.
 - ✓ Washington State allows for the electronic transmission of prescriptions.
 - ✓ The DEA is currently reviewing proposals for electronic transmission.

The board adjourned at 12:10 p.m. and reconvened at 1:10 p.m.

DISCUSSION

Service Recognition

The board recognized pharmacists who have been licensed in Washington for 50 years.

Ray D. Brown, Yakima, WA
 David A. Churness, San Pedro, CA
 William G. Clarke JR., Bremerton, WA
 Royce H. Coulso, Hobart, IN
 Donald O. Cowles, Las Vegas, NV
 Monte L. Drummond, Oroville, WA
 Edward M. Ewell, Spokane, WA
 Janet A. Ficke, Beaverton, OR
 Rodney L. Goff, Portland, OR
 Howard H. Harjes, Mount Vernon, WA
 Joseph A. Hermle, Seattle, WA
 Joseph M. Honda, Bothell, WA
 Audrey L. Lacey, Puyallup, WA
 Joshua Levy, Tacoma, WA
 Robert L. Lovitt, Hayden, ID
 Theresa A. Massie, Seattle, WA
 Donald A. Mohr, Pasco, WA
 Michael L. Murphy, Aberdeen, WA
 Ronald V. Roffler, Aberdeen, WA
 Peter A. Salagianis, Walla Walla, WA
 Larry J. Schmidt, Kelso, WA
 Robert T. Smith, Monroe, WA
 Frank D. Stuart, Seaside, OR
 Roy A. Tiegs, Puyallup, WA
 Robert K. Westenfelder, Olympia, WA
 Richard A. Worthington, Walla Walla, WA
 James P. Youngquist, Everett, WA
 J. Keith Wilson, Olympia, WA

Signature Delegation

The board reviewed delegation of signature authority related to credentialing, rulemaking and disciplinary functions for the 2009 – 2011 biennium and to formalize delegation of approval for routine collaborative agreements.

MOTION: Rosemarie Duffy moved that the board accept delegations as written. Vandana Slatter second. **MOTION CARRIED: 6-0.**

Internship Hours

Susan Teil Boyer gave the board some background on the request to address acceptance of internship hours reported by an accredited school or college of pharmacy PharmD program when the out-of-state board no longer certifies intern hours.

After the discussion the board agreed that a letter from an accredited school or college of pharmacy PharmD program when the out-of-state board no longer certifies intern hours. This letter needs to state that the experience received by student who graduate from a program has satisfied and met requirements for licensing in our state.

MOTION: Rosemarie Duffy moved that the board will accept letters from another state that indicate that the requirements satisfied by graduation from the PharmD program meets the requirements for licensure in that state. Vandana Slatter second. **MOTION CARRIED: 6-0.**

WAC 246-883-020 Identification of legend drugs for purposes of chapter 69.41 RCW

Doreen Beebe asked the board to consider draft rule language to update the legend drug list referenced in rule and make technical correction to the address and the process used for requesting a copy of the list. She explained the purpose of this rule change and answered questions.

MOTION: Rosemarie Duffy moved that the board approve the draft rule amendment as written. Dan Connolly second. **MOTION CARRIED: 6-0.**

Operating Agreement

Based on the discussion at the July 30, 2009 Susan Teil Boyer, Executive Director and Melissa Burke-Cain, AAG crafted an addendum to the draft operating agreement with the department of health. lead the discussion and were there for questions from the board regarding these addendums.

There were more comments and concerns from the board. After a long discussion between Melissa Burke-Cain and the board it was agreed that she and Susan would go back and address these more recent concerns and suggested to this Operating Agreement. The updated Operating Agreement will be brought before the board at the next board meeting.

Veterinary Drug Wholesalers

Susan Teil Boyer shared background regarding the Veterinary Wholesaler Rule in the state of Washington. She discussed a letter provided by Jim Doll with results of a survey he did that included two questions he asked other states regarding their vet wholesalers. These states fell into four different categories.

- 1) There are many states where vet legend drugs are included in the definition of prescription drugs and they are subject to those state laws regarding the dispensing of prescriptions.
- 2) Some states separate vet drug distributors and regulate them with a separate set of rules.

- 3) There are states that remove the veterinary exclusive drug distributors from the respective acts by definition and then add the word human to the definition of prescription drugs. They leave vet drugs unregulated.
- 4) Some have statutes and rules but choose to ignore them.

Susan asked the board to consider filing an inquiry to possible rule making to address the practice of drug distribution by prescription through veterinary wholesalers. The other option would be to collaborate with stakeholders to achieve compliance. (Stakeholders include: vet wholesalers, veterinarians, Dept of Agriculture, farmers, etc.)

MOTION: Christopher Barry moved that Susan Teil Boyer meet with interested parties on this issue to discuss enforcing this rule. Rebecca Hille second. **MOTION CARRIED: 6-0.**

Board-Approved Tamper-Resistant Rx Paper or Pad

Doreen Beebe asked the board to consider for approval a sample “seal of approval” design and vendor review process for implementation of House Bill 2014. There were some sample designs passed around for the board to consider.

Doreen briefed the board on her work regarding the implementation of HB2014. Doreen The board provided input and recommendations for the review/approval process for vendors of tamper resistant prescription paper and pads

MOTION: Rebecca Hille moved that the review process of a vendor requesting to provide tamper resistant paper/pad be approved with the boards suggested amendments. Vandana Slatter second.

MOTION CARRIED: 6-0.

Doreen Beebe will make the suggested amendments to the review form and send to Gary Harris, Chair for a final approval. The Board selected # 8 of the sample “seal of approval” designs.

Correspondence

The board discussed correspondence received/sent.

- Emergency Rules – Temporary Practice Permits (Secretary Profession Only).
 - ✓ Susan Teil Boyer is asking the board to consider an Emergency Rule for temporary practice permits for 60-90 days for entry level licensees waiting for their license to go through credentialing/background. These entry level applicants are unable to work for long periods of time while waiting for this process. The Emergency Rule only applies to those applicants waiting for a background checks.
- Response to Optometry Sunrise.

Christopher Barry expressed his interest and concern on this matter and would like updates.

- Teva Introduces Plan B(R) One-Step (levonorgestrel) Tablet, 1.5 mg.
- NABP eNews – September 2.
- *2009 Washington State Pandemic Influenza (H1N1, swine flu) Summit*

OPEN FORUM

Jeff Rochon with the Washington State Pharmacy Association (WSPA): commended the board on the presentation provided on pharmacy robberies at the July 30, 09 board meeting.

- ✓ The WSPA is working with the attorney general to look at the legislature efforts to increase penalties for those who commit pharmacy robberies.
- ✓ WSPA is also working to increase communication availability for patients with language barriers.
- ✓ Attorney General Rob McKenna will be speaking at the WSPA’s November meeting on prescription drug abuse and pharmacy robberies.

BUSINESS MEETING ADJOURNED

There being no further business, the board adjourned at 4:20 p.m. The Board of Pharmacy will meet again on December 10, 2009 for its regularly scheduled business meeting in Auburn, Washington

Respectfully Submitted by:

Leann George, Program Support

Approved on December 10, 2009

Gary Harris, Chair
Washington State Board of Pharmacy